

### Remarks

Applicants note that all amendments and cancellations of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the amended claims (or similar claims) in the future.

In the Office Action dated 9/8/04, the Examiner made several rejections. Each of the rejections is listed below in the order in which they are herein addressed.

- I) Claims 9, 11-18, 23-34 and 37-38 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite;
- II) Claims 9-18, 23-29 and 34-38 are rejected under 35 U.S.C. 112, first paragraph as allegedly lacking written description; and
- III) Claims 9-13, 15-18 and 23 are rejected under 35 U.S.C. 112, first paragraph as allegedly lacking enablement.

#### **I. The Claims are not indefinite**

The Examiner has rejected Claims 9, 11-18, 23-34 and 37-38 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. In particular, the Examiner has rejected Claims 9, 11-18, 23, 24, 25-29, and 34-38 as allegedly being indefinite because of the omission of essential steps of "a correlation step describing how the results of the method relate back to the preamble of the method objectives." (Office Action, pg. 2). The Applicants respectfully disagree and submit that the claims are definite as presently written. However, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have canceled Claim 11 and amended Claims 9 and 24. The amended claims

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept. 8, 2000).

include steps that relate back to the preamble. As such, the applicants respectfully request that the rejection be withdrawn.

The Examiner has further rejected Claims 24-34 and 37-38 as allegedly being indefinite because "Characterizing a tissue in a subject is not defined by the claim." (Office Action, pg. 2). The Applicants respectfully disagree and submit that the claims are definite as presently written. However, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claim 24 and canceled Claims 34-35 and 37-38. The amended claims include the claims elements of "characterizing cancer" as well as the properties of cancer included in the characterizing. The Applicants have thus defined the characterizing cancer element of the claims. As such, the applicants respectfully request that the rejection be withdrawn.

## **II. The Claims are supported by an adequate written description**

The Examiner has rejected Claims 9-18, 23-29 and 34-38 under 35 U.S.C. 112, first paragraph as allegedly lacking written description (Office Action, pg. 3). In particular, the Examiner states "Therefore, only the nucleic acid sequence consisting of SEQ ID NO:1 meets the written description of detecting the presence of HIP1 mRNA." (Office Action, pg. 3). The Applicants respectfully disagree and submit that the claims are supported by an adequate written description. However, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claim 9 and 24 to include the element of a reagent for detection of HIP1 having the nucleic acid sequence of SEQ ID NO:1. As the Examiner has admitted that the specification provide adequate written description for detection of SEQ ID NO:1 (See above), the Applicants respectfully request that the rejection be withdrawn.

## **III. The Claims are enabled**

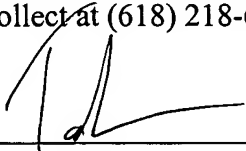
The Examiner has rejected Claims 9-13, 15-18 and 23 under 35 U.S.C. 112, first paragraph as allegedly lacking enablement (Office Action, pg. 4). In particular, the Examiner states "the specification, while being enabling for detecting colon and prostate

cancer in a subject..." (Office Action, pg. 4) The Applicants respectfully disagree and submit that the claims are enabled. However, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have canceled Claim 11 and amended Claims 9 and 24 to include the element of detecting colon and prostate cancer. As the Examiner has admitted that such embodiments are enabled (See above), the Applicants respectfully request that the rejection be withdrawn.

### CONCLUSION

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (618) 218-6900.

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